



Australian Defence Human Research Ethics Committee
CP3-6-036, Campbell Park Offices, PO Box 7912, Canberra BC ACT 2610

2016/1106993

ADHREC/OUT/2016/R26707512

16 August 2016

A/Prof Richard Fletcher

Family Action Centre
University of Newcastle
University Drive
Callaghan NSW 2308

Copy: Dr Chris May (Project Manager)
Ms Ruth Gibbins (Senior Human Research Ethics Officer, University of Newcastle)

Dear A/Prof Fletcher

Protocol 823-16 ‘SMS4dads Multi-Centre Wait List Randomised Control Trial’

Thank you for resubmitting the above research project for ethical review. This project was considered out of session by the Australian Defence Human Research Ethics Committee (ADHREC).

I am pleased to advise you that the ADHREC has granted ethical approval of this research project.

The nominated participating sites in this project are:

University of Newcastle

University of Western Australia

***Note:** If additional sites are engaged prior to the commencement of, or during the research project, the Coordinating Principal Investigator is required to notify ADHREC. Notification of withdrawn sites should also be provided to the ADHREC in a timely fashion.*

The approved documents include:

Document	Version	Date
National Ethics Application Form	3	
Information Statement for Prospective Father/Fathers	5	2 Aug 16
Participant Information Statement (Mothers)	5	2 Aug 16
SMS4dads Process Map	3	19 Jul 16

Document	Version	Date
SMS4dadsDHF Maternal Recruitment Process	2	19 Jul 16
Information Script	2	6 Jul 16
SMS4dadsDH Poster and Brochure Image		

Approval of this project from ADHREC is valid from 16 August 2016 to 15 August 2019 subject to the following conditions being met:

- The Principal Investigator will immediately report anything that might warrant review of ethical approval of the project.
- The Principal Investigator will notify the ADHREC of any event that requires an amendment/modification to the protocol or other project documents and submit any required amendments in accordance with the instructions provided by the HREC.
- The Principal Investigator will submit any necessary reports related to the safety of research participants in accordance with ADHREC policy and procedures.
- The Principal Investigator will report to the ADHREC six monthly and notify ADHREC when the project is completed at all sites in the specified formats.
- The Principal Investigator will notify the ADHREC if the project is discontinued at a participating site before the expected completion date, with reasons provided.
- The Principal Investigator will notify the ADHREC of any plan to extend the duration of the project past the approval period listed above and will submit any associated required documentation.
- The Principal Investigator will notify the ADHREC of their inability to continue and indicate the name of and contact information for a replacement.
- The return of the Principal Investigators Assurance (Attachment A) signed by all Principal Investigators.
- Prior to the commencement of the clinical phase of the research the trial is to be registered in a publicly accessible register (NS 3.3.12).

This letter constitutes ethical approval only. This project cannot proceed at any site until separate research governance authorisation has been obtained from the CEO or Delegate of the institution under whose auspices the research will be conducted at that site.

Should you have any queries about the ADHREC's consideration of your project please contact the ADHREC Secretariat on (02) 6266 3807 or adhrec@defence.gov.au.

The ADHREC wishes you every success in your research.

Yours sincerely



Ms Terri Davis
A/Director Defence Health Research

For
Mr Ian Tindall
Chair, Australian Defence Human Research Ethics Committee

Attachments:

- A. Principal Investigator's Assurance
- B. ADHREC Guidelines for Volunteers

The Australian Defence Human Research Ethics Committee is constituted and operates in accordance with the National Health and Medical Research Council's (NHMRC) *National Statement on Ethical Conduct in Human Research (2007)*.